veeda clinical research®

# BIOSIMILAR CONCLAVE 2019

31 May 2019
Novotel,
Ahmedabad,
India

"STRATEGIES FOR SUCCESSFUL BIOSIMILAR DEVELOPMENT - BENCH TO BEDSIDE"

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**Biosimilar Conclave 2019, is an initiative by Veeda Clinical Research** to bring pharma and biotech companies at a common platform which will address **issues around biosimilar development & characterization, challenges of establishing bio similarity, global regulatory pathways, clinical program and commercialization strategies.**

This national level conclave welcomes all the stakeholders and researchers to share their experiences and views on strategies for successful Biosimilar development, **its approval and commercialization.**

## CONCLAVE OBJECTIVES AND BENEFITS OF ATTENDING

- Current challenges and opportunities - strategies to develop Biosimilar
- Focused strategies for region specific regulatory requirements and approaches to increase speed of entry and compliance
- Considerations for the analytical similarity assessments when designing a Biosimilar development program
- Unique attributes, challenges, and complexities of biosimilar clinical program to obtain clinical data to address the clinical similarity between reference and comparator product
- Critical quality parameters and the assessment of their impact on potency, PK, immunogenicity, and safety

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| Time | Program At A Glance |
|---|---|
| 09:00 - 09:45 | **Registration & Breakfast** |
| 09:45 - 11:15 | Biosimilar - Past, present & Future |
| | Development of Biosimilars considering Changing Regulatory Requirements |
| | Considerations for establishing analytical similarity in biosimilars |
| 11:15 - 11:35 | **Refreshment Break** |
| 11:35 - 12:55 | Biosimilar Trials in India |
| | **Panel Discussion:**<br>• Regulatory Perspectives for Successful BioSimilars development<br>• Differences between approaches EU/FDA and Indian regulation<br>• Global harmonization in quality and regulatory requirements<br>• What are the key to new international developments? What can we adapt from those?<br>• Strategies for improving regulatory expertise and cross-nation support for promoting regulatory policy innovation<br>• Examine current thinking from industry and regulators on requirements for post-approval changes to biosimilar products<br>• Current regulatory challenges for the expedition of biosimilars |

| Time | Program At A Glance |
|---|---|
| 12:55 - 13:55 | **Networking Lunch** |
| 13:55 - 15:15 | Bioanalytical challenges of the large molecule - Application of LCMS method for Qualitative and Quantitative analysis of Biosim |
| | Elements of robust R&D performance strategies |
| | Biosimilar Clinical Programs Strategies - Unique challenges while designing and execution |
| 15:15 - 15:35 | **Refreshment Break** |
| 15:35 - 16:45 | Interchangeability of biosimilar products |
| | **Panel Discussion: Bringing biosimilar to market**<br>• Challenge of establishing biosimilarity and different regulatory approach<br>• Corporate strategies to develop biosimilars<br>• Market Pricing and Commercialization strategies for Biosimilars - how developing markets differ from developed market |
| 16:45 - 16:55 | Closing Remarks |
| 16:55 - 17:30 | **High Tea** |

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# WHO WILL ATTEND?

VPs, Directors, Heads, Managers, Senior Scientists Professionals with intermediate to Advanced knowledge and experience in the following:

Biotechnology | Bioanalytics | Biomanufacturing | Biopharmaceuticals | Bioprocessing | Biosimilars | Biotherapeutics | Cell Line |Clinical Immunology | Development | Commercial Biologics | Drug Safety & Risk Management | Expression Systems | Market Entry Immunogenicity Testing | Partnering and Licensing |Patient Safety | Product Development | Protein Characterization | Scale-up Processes | Regulatory | Quality Assurance | Regulatory Affairs | CMC

## TERM & CONDITION

### Conclave Registration:

- Registration is mandatory.
- Registration includes conclave documentation, refreshments & lunch.
- Registration confirmation will be given on a first come first serve basis.

### Data Protection:

- The personal information shown and/or provided by you will be used to keep you up to date with developments in the industry.
- Your details will be completely confidential and will be not shared with any other party for any purpose.

### Changes to conclave & Agenda:

- Veeda Clinical Research reserves the right to Admission, postpone or cancel an event, to change the location or alter the advertised speakers for an event.
- Veeda Clinical Research is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.
- In the event that a conclave is canceled, Veeda Clinical Research is not liable for any costs incurred by delegates in connection with their attendance.
- Control to alter the content and timing of the programme, venue or the identity of the speakers without any liability to the delegates.t
- Changes to the agenda will be updated on our website as soon as possible.

**To register :**
**Write us at**
**EVENTS@VEEDACR.COM**